AGENCY

Bridging The Gap:

The European Union Path Towards Streamlined Patent Law and Enhanced Access to Medicines

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Summary

The European Commission has presented a series of proposals aimed at reforming patent laws within the EU, with a focus on Intellectual Property (IP) and Supplementary Protection Certificates (SPCs). The objective is to create a more transparent, streamlined, and harmonised system that encourages innovation, facilitates research and development (R&D), and improves access to essential medicines. By addressing issues related to standard essential patents (SEPs), compulsory licensing during crises, and SPCs, the proposed reforms seek to strike a balance between protecting intellectual property rights and ensuring fair and reasonable access to life-saving treatments. As these proposals are subject to further discussions and agreements, the EU aims to create a robust and sustainable healthcare system that benefits both innovators and patients.

Introduction

The European Union (EU) continues to deliver on the Action Plan on Intellectual Property (IP) of November 2020 to implement, protect, and improve the IP legal framework in the Union.

However, recent events have shown that EU patent law remains fragmented, and current legislation fails to keep the pace of emerging technologies in a global, fast-evolving scenario. Moreover, the new legislation is intended to complement the Unitary Patent System, whose launch takes place in June 2023.

On April 27, 2023, the European Commission proposed new rules to address these issues. The new rules are encapsulated into three proposals for regulation, covering (i) patents relating to industry standards, (ii) compulsory licensing of patents in crises, and (iii) the revision of the legislation on supplementary protection certificates.

This research aims to explore the three pieces of legislation to analyse their impact on two significant aspects: (a) access to medicines and (b) R&D and innovation.

(i) Standard Essential Patents (SEPs)

A standard essential patent is a type of patent that safeguards the technology necessary for implementing a standard. A standard, also known as a "technical standard" or "technical interoperability standard," refers to an agreed-upon or established technical specification. Examples of such standards include 5G and WiFi for telecommunications, audio and video compression formats like MPEG and HEVC, storage and exchange

technologies such as CD and DVD, photo formats like JPEG, and home audio and video interoperability systems like HAVi.

Typically, a patent owner can decide whether to grant licenses to other entities to utilise their innovation. However, when patented technology is incorporated into a standard, the patent holder gains significant market power over implementers of that standard. As a result, patent holders participating in standard development must commit to licensing their standard essential patents (SEPs) under fair, reasonable, and non-discriminatory (FRAND) terms.

Unfortunately, the current European Union (EU) system has led to prolonged disputes and litigation due to a lack of transparency and time-consuming, costly negotiations, particularly with large implementers. The European Commission has identified several factors contributing to these problems:

- **Lack of transparency** regarding the ownership, applicability, and essentiality of SEPs, leads to an over-declaration of SEPs, where patents are claimed as essential to a standard even when they are not.

- **Limited information** on SEP license fees (FRAND royalties) makes it difficult for implementers with little expertise or resources to assess whether the licensing terms offered by SEP holders are truly FRAND.

- **Lengthy and costly licensing disputes** that consume significant time and resources. The mere threat of an injunction or the prospect of a lengthy court procedure can exert undue pressure on implementers, especially small and medium-sized enterprises (SMEs), to agree to license terms that may not be fair or reasonable. Litigation also burdens both parties with substantial costs and time commitments.

To address these issues, the proposed SEP reform aims to establish a more balanced and transparent framework. The regulation proposal has two main objectives:

1. Ensuring that both EU SEP holders and implementers engage in innovation within the EU, manufacture and sell products in the EU, and remain competitive in non-EU markets.
2. Ensuring that end users, including SMEs and consumers, can access products based on the latest standardised technologies at reasonable prices while adequately rewarding the underlying innovation.

To achieve these goals, the proposal includes the following key elements:

(i) SEP register, database, and essentiality checks: creating a mandatory register maintained by the European Union Intellectual Property Office (EUIPO) where SEP holders must record their SEPs and provide details about patents and standards. Selected SEPs will undergo a non-binding essentiality check. An electronic database will also be established to contain information on aggregate royalties, FRAND terms and conditions, licensing programs, and collective licensing initiatives, among other data.

(ii) SEP aggregate royalty: SEP holders can notify the expected maximum aggregate royalty in the register. Alternatively, SEP holders and implementers can seek

recommendations from a conciliator regarding a non-binding aggregate royalty.
(iii) FRAND determination: Implement an expert-driven, time-limited, out-of-court dispute resolution mechanism that SEP holders and implementers can utilise during FRAND license negotiations. In specific circumstances, and with certain safeguards concerning commitment and access to justice, SEP holders and implementers must attempt to agree on a royalty through the FRAND determination process within a maximum of nine months before resorting to litigation. The FRAND determination serves as a safe harbour for implementers, allowing them to negotiate without the pressure of potential litigation. It also helps limit the duration of lengthy licensing negotiations for SEP holders.

(iv) SME support measures: Provision of free advisory services, reduced registration fees for SEPs, essentiality checks, access to the SEP register, and promotion of more favourable FRAND terms and conditions specifically for SMEs.

(v) Establishment of a "Competence Centre" at the EUIPO responsible for administering the elements, including the registry, database, essentiality checks, aggregate royalty, FRAND determination, and SME support services.

Analysis of the Impact on R&D and Innovation

By promoting innovation within the EU, the regulation encourages R&D activities and the development of new technologies. It also incentivises companies to invest in research and innovation to maintain competitiveness. Simultaneously, the proposal aims to ensure that end users, including SMEs and consumers, can access products based on the latest standardised technologies at reasonable prices. Doing so facilitates the adoption and diffusion of innovative technologies, which can drive further R&D and innovation. This provision mainly benefits SMEs, giving them access to cutting-edge technologies that may otherwise be cost-prohibitive.

Nonetheless, two aspects need to be addressed with attention:

(a) Fragmentation and barriers to competition: SEPs can lead to fragmentation when different companies hold patents on essential technologies within the same standard. This fragmentation can create barriers to competition, as companies may need to obtain licenses from multiple patent holders to develop products. It can also result in legal disputes and hinder the development of standardised technologies. The new legislation must aim at addressing this issue.

(b) Slow adoption of new standards: The presence of SEPs can sometimes slow the adoption of new standards. Companies may be hesitant to adopt new technologies if they anticipate facing licensing challenges or uncertainty regarding the availability of essential patents. This delay can impact the pace of innovation and the overall advancement of technologies.

It is important to note that the impact of SEPs on R&D and innovation can vary depending on specific industries, market dynamics, and the behaviour of patent holders. Balancing the need for fair compensation with fostering competition and innovation remains challenging in SEPs.

Analysis of the Impact on Access to Medicines

The new proposal addresses access to medicines by balancing the interests of intellectual property holders (SEP holders) and implementers while ensuring that end users, including SMEs and consumers, can access products based on the latest standardised technologies at reasonable prices.

Creating a mandatory register maintained by the European Union Intellectual Property Office (EUIPO) can positively impact access to medicines. The register increases transparency by requiring SEP holders to record their SEPs and provide patent and standard details. It allows potential implementers to identify patents essential for implementing a particular technology. This can facilitate negotiations and licensing agreements, potentially leading to increased access to medicines.

The option for SEP holders to notify the expected maximum aggregate royalty in the register, or seek recommendations from a conciliator, can contribute to a fairer and more predictable licensing process. This can prevent excessive royalty demands that may hinder access to medicines. By clarifying potential licensing costs, implementers can make informed decisions and negotiate reasonable terms, benefiting drug access.

Implementing an expert-driven, time-limited, out-of-court dispute resolution mechanism for FRAND (Fair, Reasonable, and Non-Discriminatory) license negotiations is an essential aspect of the proposal. Establishing a process that encourages negotiation before resorting to litigation reduces the risk of lengthy legal battles that could delay the availability of medicines. The FRAND determination process also serves as a safe harbour for implementers, providing a framework to negotiate without the pressure of potential litigation. This can help streamline licensing negotiations and ultimately improve access to medicines.

However, the proposal needs to address two main issues furtherly. Notably:

(a) High costs: Patents granted for pharmaceutical innovations often increase medicines' prices, particularly during the exclusivity period or in times of high demand. This can pose a barrier to access, especially for individuals in low-income countries or those without adequate health insurance coverage.

(b) Patent thickets: In some cases, multiple patents may cover a single medicine, leading to a situation called "patent thickets." These thickets can create legal complexities and barriers for generic manufacturers, delaying the entry of affordable generic versions into the market and hindering access to affordable medicines.

It is crucial to consider the specific context and dynamics of each situation when assessing the impact of the new regulation on access to medicines. Balancing intellectual property rights with public health concerns remains an ongoing challenge, especially in times of unpredicted crises like the one the world recently experienced with the COVID-19 pandemic.

(ii) Compulsory licensing of patents in crises

The proposed legislation regarding crisis management represents a significant advancement in the European Union's ongoing efforts to standardise patent laws within the bloc. Establishing Unitary Patents and the European Patent Court has been a substantial step towards this goal. Although individual member states have their compulsory licensing schemes, there is still room for greater harmonisation among European countries.

The European Commission recognises the crucial role of intellectual property rights, particularly patent rights, in ensuring access to medicines, especially during public health emergencies like the COVID-19 pandemic. This crisis highlighted the conflict between the need to protect and incentivise innovation and the desire to make essential products widely accessible. To address this tension, the Commission acknowledges that patent law already provides a solution: compulsory licensing.

Compulsory licensing allows third parties to use a patent without seeking permission from the patent owner. When a compulsory license is granted, a government permits a third party to produce and distribute a patented product without the patent owner's consent. The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) explicitly recognises compulsory licenses as part of the flexibilities afforded.

The new proposal introduces a Union compulsory licensing scheme that applies to patents (including patent applications), utility models, and supplementary protection certificates in force within one or more European Union member states.

The authority to grant such licenses will be vested in the Commission. The Commission may issue a Union compulsory license in crisis or emergencies.

The license will possess the following characteristics: (i) it will be non-exclusive and non-transferable; (ii) its scope and duration will be limited to the crisis period; (iii) it will strictly apply to the relevant activities involving crisis-related products within the Union; (iv) it will be granted only in exchange for appropriate compensation; (v) its territorial coverage will be limited to the Union; and (vi) it will be granted solely to entities capable of utilising the protected invention in a manner that allows for the proper execution of the relevant activities.

The COVID-19 pandemic demonstrated the consequences of fragmentation across countries, leading to divergent policies among member states concerning crisis-related products. By implementing the proposed Regulation, companies should be able to benefit from a unified compulsory licensing scheme across Europe, ensuring the smooth functioning of the single market during crises.

These efforts and the proposed legislation align with the European Commission's previous emphasis, expressed in 2020, on establishing effective compulsory licensing systems.

Analysis of the Impact on R&D and Innovation

The impact of the proposed legislation on innovation and R&D investment can be multifaceted. On the one hand, compulsory licensing during crises can provide opportunities for additional players to contribute to developing and producing critical products. This increased collaboration and utilisation of patented technologies can lead to accelerated innovation and novel solutions. On the other hand, the introduction of compulsory licensing may raise concerns for patent holders, as it limits their exclusive rights and potentially reduces the financial returns on their investments in R&D. The appropriate balance between incentivising innovation and ensuring access to essential products will be crucial to maintain a favourable environment for R&D investment and long-term innovation.
Specifically, the possibility of compulsory licensing may create uncertainty and reduce the incentives for pharmaceutical companies to invest in high-cost and high-risk R&D projects. The prospect of having their patented inventions forcibly licensed could undermine the business case for pursuing innovative treatments, particularly in therapeutic areas with smaller patient populations or longer development timelines.

The reduced financial incentives from compulsory licensing may encourage pharmaceutical companies to focus on incremental innovations or modifications of existing products. This could lead to a decrease in breakthrough discoveries and transformative treatments. Companies may prioritise incremental improvements to extend the exclusivity of existing patents rather than pursuing riskier and more disruptive R&D endeavours.

Positive impact on innovation dynamics: Some argue that compulsory licensing can foster competition and stimulate innovation by increasing access to patented technologies. When multiple companies can produce and market generic versions of a patented invention, it can lead to price competition and accelerated technology development. This dynamic can encourage innovators to continually push the boundaries of scientific and technological advancements to stay ahead of competitors.

Using compulsory licensing in specific regions or countries may lead to regional disparities in R&D activities. Companies could prioritise investments in countries with more robust intellectual property protection, potentially leaving areas with more frequent use of compulsory licensing with fewer R&D opportunities and reduced access to cutting-edge innovations.

In general, it is essential to note that the impact of compulsory licensing on R&D and innovation is a complex issue, and its effects may vary depending on the specific circumstances, concurrent regulatory frameworks, and industry dynamics.

Analysis of the Impact on Access to Medicines

The proposed legislation on compulsory licensing can significantly impact access to medicines, particularly in improving affordability and availability. Here are some critical implications:

(a) Increased affordability: Compulsory licensing allows generic manufacturers to produce and distribute affordable versions of patented medicines. Breaking the monopoly

held by the patent holder introduces competition into the market, which can drive down prices. This increased affordability can make essential drugs more accessible to individuals and healthcare systems, particularly in low- and middle-income countries where the cost of patented medications may be prohibitive.

(b) Expanded access to treatment: Compulsory licensing can help overcome barriers to entry for populations that would otherwise be unable to afford the patented medicines. This is particularly critical for life-saving drugs, where access to affordable treatment can directly impact public health outcomes. It enables governments to ensure that necessary medications are available to their citizens, addressing health inequalities and improving overall healthcare access.

(c) Response to public health emergencies: Compulsory licensing plays a crucial role in responding to public health emergencies, such as epidemics or pandemics. It allows governments to quickly authorise the production of essential medications to address the health crisis. By removing patent barriers, compulsory licensing can expedite the availability of treatments, vaccines, and diagnostics needed to control the spread of diseases and save lives.

(d) Negotiating power and pricing transparency: The possibility of compulsory licensing can increase governments' leverage in negotiating fair pricing agreements with pharmaceutical companies. It creates a stronger bargaining position by demonstrating a willingness to authorise generic production if prices are unreasonable. Additionally, compulsory licensing can bring greater transparency to pricing practices and stimulate discussions on fair and equitable pricing of medicines.

(e) Encouraging innovation and competition: While there may be concerns about the impact of compulsory licensing on pharmaceutical innovation, proponents argue that it can foster innovation. Introducing competition through generic manufacturing can incentivise research and development (R&D) investment as pharmaceutical companies strive to develop improved and more cost-effective treatments to stay ahead in the market.

(f) International implications: Compulsory licensing can generate international discussions and potential trade-related disputes. Countries that employ compulsory licensing may face challenges or criticisms from patent-holding countries, particularly those with strong intellectual property protection regimes. These disputes highlight the tension between public health needs and intellectual property rights, and they can influence global discussions on access to medicines and intellectual property frameworks.

Overall, the proposed legislation needs to be effectively evaluated on a prominent aspect: its effectiveness in balancing compulsory licensing with the need to incentivise pharmaceutical innovation and ensure the sustainable development of new treatments.

(iii) Supplementary Protection Certificates (SPCs)

The current system for filing Supplementary Protection Certificate (SPC) applications involves filing at the national level, requiring separate applications at each national patent office where protection is sought. This increases applicants' costs due to multiple states'

multiplied legal and official fees. It also creates uncertainty as different national patent offices may make diverging decisions on equivalent SPC applications. To address these issues, the Commission has proposed two solutions:

1. **Introducing a centralised examination procedure for SPCs:** Under this proposal, SPC examination would be conducted centrally by the European Union Intellectual Property Office (EUIPO), with assistance from experienced examiners from national patent offices. Once the central examination is complete, a bundle of national SPCs would be granted or refused accordingly. To file a centralised SPC application, the basic patent must be a European Patent granted by the European Patent Office (EPO), including Unitary Patents, and the marketing authorisation relied upon must be a centralised one given under specific regulations. The proposal aims to close the option of filing SPCs at national patent offices after obtaining a centralised marketing authorisation. The examination process involves a panel of three examiners, including two from different national patent offices and one from the EUIPO. The outcome is an "examination opinion" binding on national patent offices. However, the applicant can appeal negative or partially negative opinions.
2. **Introducing a unitary SPC (USPC):** This proposal mirrors the concept of the Unitary Patent system. To obtain a USPC, the basic patent must be a Unitary Patent, and the marketing authorisation must be a centralised one. The same centralised examination procedure used for SPCs would apply to USPCs. Third parties would be able to file observations and oppositions at the EUIPO. However, as Unitary Patents currently do not cover all EU member states, a "combined" application would be filed for a USPC, including a request for a USPC and national SPCs in non-unitary patent states. After the grant, a third party could challenge the USPC's validity at the EUIPO or raise a counterclaim at the Unified Patent Court (UPC) if the SPC holder initiates enforcement proceedings.

The proposals state that they intend to keep the substantive aspects of SPC law the same. However, they include revisions and additions to the statute that could impact the law. The proposals acknowledge the need to clarify certain aspects of SPC law through pending referrals to the Court of Justice of the European Union (CJEU). ***Including new recitals in the statute raises questions about the necessity of these changes if the aim is to avoid divergence through the centralised examination without modifying the law.***

It is important to note that these proposals are subject to discussion and agreement by the European Parliament and Council before their adoption and entry into force.

Analysis of the Impact on Access to Medicines

The proposed introduction of a centralised examination procedure for Supplementary Protection Certificates (SPCs) and the concept of a unitary SPC (USPC) can positively and negatively impact access to medicines.

On the positive side, a centralised examination procedure conducted by the European Union Intellectual Property Office (EUIPO) with assistance from experienced examiners could lead to greater harmonisation and consistency in the granting or refusing SPCs. This could streamline the process and reduce the administrative burden for applicants.

Additionally, the involvement of examiners from national patent offices can contribute to the expertise and knowledge applied during the examination process.

Introducing a USPC, like the concept of Unitary Patents, may offer benefits such as a single protection title covering multiple EU member states, reducing the complexity and costs of obtaining separate national SPCs.

However, there are concerns regarding the potential impact on access to medicines. One potential drawback is the limitation on filing SPCs at national patent offices after obtaining a centralised marketing authorisation. This may restrict the options available to applicants, potentially leading to delays or difficulties obtaining SPC protection in certain circumstances.
Furthermore, the centralised examination procedure may introduce additional bureaucracy and potential delays in the SPC application process. While harmonisation is desirable, if the examination process becomes excessively lengthy or burdensome, it could impede the timely market entry of innovative medicines and delay patient access.

The ability for third parties to file observations and oppositions at the EUIPO is a positive aspect as it allows for increased scrutiny and potential challenges to ensure the validity and exclusivity of SPCs. However, this could also result in additional legal proceedings and potential disputes, further delaying the availability of generic or biosimilar alternatives.

It is important to note that the proposals state they intend to keep the substantive aspects of SPC law the same. However, the revisions and additions to the statute and the need to clarify some elements through pending referrals to the Court of Justice of the European Union (CJEU) raise questions about the necessity of these changes and their potential impact on the legal framework.

Overall, while the proposed centralised examination procedure and the concept of USPCs may benefit harmonisation and streamlined processes, careful consideration is necessary to ensure that these changes do not unduly hinder access to medicines or create unnecessary barriers for innovators and generic manufacturers. Balancing the interests of intellectual property protection and public health is crucial to maintain a robust and sustainable healthcare system.

Analysis of the Impact on R&D and Innovation

The introduction of a centralised examination procedure for Supplementary Protection Certificates (SPCs) and the proposal for a unitary SPC (USPC) can have several impacts on research and development (R&D) as well as innovation. Here are some potential effects:

1. Streamlined Process: The centralisation of the SPC examination under the European Union Intellectual Property Office (EUIPO) could result in a more efficient and standardised process. This could reduce the administrative burden and complexities associated with filing SPCs in different national patent offices, potentially saving time and resources for applicants.

2. Increased Legal Certainty: With a central examination procedure, there is the possibility of increased legal certainty regarding the grant or refusal of SPCs. The binding examination

opinion provided by the panel of examiners can help applicants understand the likelihood of obtaining SPC protection. This clarity may assist in making informed decisions related to R&D investments and commercialisation strategies.

3. Harmonization of Standards: The centralisation of the SPC examination could contribute to harmonising the standards for granting SPCs across the European Union (EU). This harmonisation may facilitate a more consistent approach to SPC protection, encouraging innovation and reducing discrepancies in SPC eligibility criteria between different member states.

4. Impact on Patent Strategy: The requirement for a Unitary Patent or a centralised marketing authorisation for USPCs may influence patent filing strategies. Companies may choose to prioritise obtaining Unitary Patents and central marketing authorisations to take advantage of the benefits offered by the USPC system. This could impact the allocation of resources and the geographic scope of patent protection sought.

5. Influence on R&D Investments: The proposed changes could influence companies' decisions regarding R&D investments. The potential for a streamlined process and increased legal certainty may provide a more favourable environment for R&D activities, especially in the pharmaceutical and biotechnology sectors, where SPCs play a crucial role in extending exclusivity periods.

6. Challenges and Opportunities: Introducing a centralised examination procedure and the USPC system may also bring challenges and opportunities for third parties. Increased accessibility for third-party observations and oppositions at the EUIPO could promote a more transparent and inclusive approach. However, challenges to USPC validity or counterclaims raised at the Unified Patent Court could also introduce complexities and potential disputes.

Overall, the impact of these proposals on R&D and innovation would depend on various factors, including the implementation details, the level of harmonisation achieved, and the practical implications for applicants and third parties. These proposals streamline the SPC process and provide more clarity, potentially supporting EU R&D and innovation efforts.

Summary Conclusions

1. Fragmented EU Patent Law: The EU's patent law remains fragmented, leading to disputes and inefficiencies in licensing, particularly with standard essential patents (SEPs). The proposed reforms aim to address these issues and create a more transparent and balanced framework.

2. Impact on R&D and Innovation: The reforms are likely to have both positive and negative effects on research and innovation. They may promote innovation by facilitating access to cutting-edge technologies for SMEs and increasing collaboration. However, concerns exist regarding potential delays in the adoption of new standards and reduced incentives for R&D investments due to compulsory licensing.

3. Access to Medicines: The proposals aim to improve access to medicines by promoting transparency in licensing, reducing costs through compulsory licensing during crises, and

fostering competition. However, concerns remain about affordability during exclusivity periods and potential delays in generic market entry due to patent thickets.

4. Compulsory Licensing in Crises: The introduction of a Union compulsory licensing scheme for crises can ensure access to essential products during emergencies. However, balancing public health needs and incentivizing innovation remains a challenge, and international implications and disputes may arise.

5. Supplementary Protection Certificates (SPCs): The proposed centralised examination procedure and the concept of a unitary SPC (USPC) aim to harmonise and streamline the SPC application process. While they may offer benefits like increased legal certainty and streamlined processes, concerns exist about potential barriers to access and impacts on R&D strategies.

6. Balancing Intellectual Property Rights and Public Health: Throughout the proposals, the challenge lies in striking a balance between protecting intellectual property rights and ensuring access to essential products, especially in times of crises.

7. Complexities and Specific Context: The impact of these reforms is multifaceted and varies based on specific industries, market dynamics, and regional contexts. Careful consideration is needed to address the complexities and ensure the sustainable development of new treatments while safeguarding public health interests.